

## § 866.3500

## 21 CFR Ch. I (4–1–12 Edition)

### § 866.3500 *Rickettsia* serological reagents.

(a) *Identification.* *Rickettsia* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *rickettsia* in serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens. The identification aids in the diagnosis of diseases caused by virus-like bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on these diseases. *Rickettsia* are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

### § 866.3510 Rubella virus serological reagents.

(a) *Identification.* Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubella virus in serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) *Classification.* Class II. The special controls for this device are:

(1) National Committee for Clinical Laboratory Standards:

(i) 1/LA6 “Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of the Test Products in the Clinical Laboratory, October 1997,”

(ii) 1/LA18 “Specifications for Immunological Testing for Infectious Diseases, December 1994,”

(iii) D13 “Agglutination Characteristics, Methodology, Limitations, and Clinical Validation, October 1993,”

(iv) EP5 “Evaluation of Precision Performance of Clinical Chemistry Devices, February 1999,” and

(v) EP10 “Preliminary Evaluation of the Linearity of Quantitative Clinical Laboratory Methods, May 1998,”

(2) Centers for Disease Control’s:

(i) Low Titer Rubella Standard,

(ii) Reference Panel of Well Characterized Rubella Sera, and

(3) World Health Organization’s International Rubella Standard.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

### § 866.3520 Rubella (measles) virus serological reagents.

(a) *Identification.* Rubella (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubella virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

### § 866.3550 *Salmonella* spp. serological reagents.

(a) *Identification.* *Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Salmonella* spp. directly from clinical specimens or cultured